IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEBRASKA

) CASE NO. 4:05CV3248
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) PLAINTIFF'S BRIEF IN
) SUPPORT OF MOTION FO
) SUMMARY JUDGMENT
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STATEMENT OF MATERIAL FACTS

- 1. This is an appeal from a final order issued by the Secretary of the United States

 Department of Health and Human Services on August 24, 2005. (Complaint ¶ 16) (AR 0193).
- 2. Plaintiff (Costa) is a resident of Gothenburg, Dawson County, Nebraska. The events giving rise to Costa's underlying claim occurred in Nebraska. (Complaint \P 2, 3) (AR 001)
- 3. Costa was the subject of an Adverse Action Report filed with the National Practitioner Data Bank by John Johnson (Johnson), a hospital administrator for Gothenburg Memorial Hospital (GMH) in Gothenburg, Nebraska. (Complaint ¶ 3) (AR 0001)
- 4. Defendant Michael O. Leavitt is the Secretary of Health and Human Services (Secretary), duly appointed, qualified and acting as the administrative head of such agency. (Complaint ¶ 4) (Answer ¶ 4)

- 5. Defendant United States Department of Health and Human Services is the federal agency designated under the Health Care Quality Improvement Act of 1986, as amended, 42 U.S.C. § 11101 et seq. (HCQIA) to handle and oversee the receipt and filing of reports from health care entities such as GMH which reports include Adverse Action Reports. (Complaint ¶ 5) (Answer ¶ 5)
- 6. The National Practitioner Data Bank (Data Bank) is administered by the United States Department of Health and Human Services (Department). (Complaint ¶ 6) (Answer ¶ 6)
- 7. Pursuant to the HCQIA, certain information related to a physician's licensure, privileges, credentials and adverse medical malpractice claims must be reported to the Data Bank. The Data Bank functions as a clearinghouse to obtain and disseminate information on adverse actions taken against physicians. (Complaint ¶ 7) (Answer ¶ 7)
- 8. On or about July 21, 2004, Johnson filed an Adverse Action Report (NPDB Report 5500000034272447) with the Data Bank in which Johnson claimed that Costa had surrendered his clinical privileges at GMH while under investigation by a state agency. (Complaint \P 8) (Answer \P 8)
- 9. On or about August 10, 2004, Costa submitted a responsive Subject Statement to the Data Bank and placed Report 5500000034272447 in disputed status challenging both the factual accuracy of the report and whether the report was submitted in accordance with Data Bank reporting requirements. (Complaint ¶ 10) (Answer ¶ 10)
- 10. On or about August 10, 2004, Costa requested that Johnson and GMH retract or void the Adverse Action Report. After Johnson and GMH refused to retract or void the report,

Costa, on or about October 5, 2004, sought Secretarial Review of the disputed report. (Complaint ¶ 11) (Answer ¶ 11) (AR 0018-0019)

- 11. On or about November 29, 2004, Johnson and GMH were instructed by Joyce Ann Brentley, J.D., LL.M., a Dispute Resolution Manager with the Practitioner Data Banks Branch, to void or correct the disputed Adverse Action Report. (Complaint ¶ 12) (Answer ¶ 12) (AR 0031-0032)
- 12. On or about March 10, 2005, Johnson and GMH were again instructed by Joyce Ann Brentley to void or correct the disputed Adverse Action Report. (Complaint ¶ 13) (Answer ¶ 13) (AR 0078-0079)
- 13. On or about April 6, 2005, Johnson submitted to the Data Bank a Correction Adverse Action Report 5500000037166652 (Correction Report). (Complaint ¶ 14) (Answer ¶ 14) (AR 0087-0089)
- 14. On or about April 19, 2005, Costa submitted a responsive Subject Statement to the Data Bank and placed Report 5500000037166652 in disputed status challenging both the factual accuracy of the report and whether the report was submitted in accordance with Data Bank reporting requirements. (Complaint ¶ 15) (Answer ¶ 15) (AR 0103-0104)
- 15. On August 24, 2005, the Secretary issued his Secretarial Review Decision finding and ordering that Report 5500000037166652 was accurate and should have been filed.

 Consequently, Costa's request that Report 5500000037166652 be voided was denied.

 (Complaint ¶ 16) (Answer ¶ 16) (AR 0193-0197)
- 16. As a result of the foregoing action by the Secretary, the Correction Report,Costa's Subject Statement, and the Secretarial Review Decision have been entered in the Data

Bank for dissemination to all entities or queriers who have received a Data Bank report concerning Costa in the past three years. Further, the Correction Report, Costa's Subject Statement, and the Secretarial Review Decision will be disseminated to all future entities or queriers who request a Data Bank report concerning Costa. (Complaint ¶ 17) (Answer ¶ 17)

- 17. Costa is a family practice physician licensed in the state of Nebraska. (AR 001)
- 18. Costa had staff privileges at GMH until July 6, 2004. (AR0119) (The letter of resignation contains a typographical error in the date reflecting June (sic) instead of July.)
- 19. In the spring of 2004, Costa sought to have members of the hospital board recalled through the mechanism of a recall petition. (AR 0120-0121) Pursuant to Neb. Rev. Stat. § 32-1303, Costa set forth the concerns underlying the purpose for the recall election. (AR 0120-0121) Costa's concerns as reflected on the recall petition included: 1) the failure of the members of the Board to oversee the current administrator; 2) the failure to investigate the general decline of quality employees employed at the hospital; 3) the decline in the general quality of care provided by GMH; and 4) the failure to provide proper financial supervision. (AR 0120-0121)
- 20. Also in the spring of 2004, Costa applied to renew his privileges at GMH. Such a reapplication process is mandated by GMH bylaws for those medical staff members whose privileges are going to expire. (AR 0060) (AR 0134)
- 21. After a medical staff meeting on July 2, 2004, Costa elected to withdraw his application for renewal of clinical privileges at the hospital when it became apparent to him that small-town politics would continue to adversely impact his professional practice and his personal life. (AR 003) (AR 0064-0065)

22. Thereafter, Johnson filed with the Data Bank the first Adverse Action Report claiming that Costa had surrendered his privileges while under investigation by a state agency, namely the Nebraska Department of Health and Human Services. (AR 0002) In the Adverse Action Report, Johnson alleged:

Dr. Costa withdrew his medical staff application and voluntarily surrendered his current privileges. There have been concerns of alledged [sic] unprofessional conduct, HIPPA [sic] violations, and other concerns of quality of care currently under investigation by the Nebraska Health and Human Services, Regulation and Licensure, Division of Investigations.

(AR 0002)

- 23. Costa's official response by way of a Subject Statement on August 10, 2004 indicated: 1) there was no investigation being conducted by the Nebraska Department of Health and Human Services; 2) the report by Johnson to the Data Bank was inaccurate; 3) the report by Johnson to the Data Bank was not a reportable event; and 4) the report by Johnson to the Data Bank was done in retaliation for Costa's efforts to have certain members of the hospital board recalled. (AR 0002-0003) (Emphasis in original.)
- 24. On November 29, 2004, the Dispute Resolution Manager, Joyce Ann Brentley, noted in a letter to Johnson that the adverse action report as filed by Johnson did not set forth a reportable event. "Nowhere in the record does GMH reference its <u>own</u> investigation. If GMH was not conducting or about to conduct an investigation at the time of Dr. Costa's voluntary surrender, his voluntary surrender would not be reportable[.] ... If this is the case, GMH should void the report from the NPDB." (AR 0031-0032)
- 25. In said letter, Joyce Ann Brentley instructed Johnson that if Costa was under investigation by GMH at the time he surrendered his privileges, or if Costa surrendered his

privileges to avoid an investigation by GMH, then GMH should submit documentation of that fact. "Written confirmation could include such documents as a copy of the notice to Dr. Costa of the hearing or a copy of minutes of the investigation committee." (AR 0031)

- 26. On December 27, 2004, without voiding the Adverse Action Report or providing the written documentation requested by Ms. Brentley, Johnson sent a lengthy recitation of "events" which Johnson claimed occurred prior to Costa's surrender of privileges and which Johnson claimed supported his opinion that Costa was "under investigation" by GMH. Said letter contained no supporting documentation. (AR 0043-0046)
- 27. On December 28, 2004, Costa also responded to the November 29, 2004 letter from Joyce Ann Brentley to Johnson. In that letter, Costa furnished to Ms. Brentley those portions of the hospital bylaws which identified the two forms of contemporaneous documentation Johnson should have been able to submit if in fact an investigation was being conducted at the time of surrender. (AR0048-0055)
- 28. The GMH bylaws mandate that if an investigation is initiated "a written request" to the Executive Committee shall be made "making specific reference to the activity or conduct which gave rise to the request." Additionally, the bylaws provide: "The individual with respect to whom an investigation has been requested shall have an opportunity to meet with the Executive Committee before it makes its report." (AR 0138-0140)
- 29. Costa was never notified of an investigation and was never offered an opportunity to meet with the Executive Committee concerning an investigation. (AR 0050-0051)
- 30. On March 4, 2005, Johnson responded to Costa's December 28, 2004 submission by way of a letter to Joyce Ann Brentley. In the letter, Johnson claimed hat GMH is not bound

by its own bylaws. "The term 'investigation' however, is broad, and is not limited to that set forth in the medical staff bylaws." (AR 0061)

- 31. Johnson submitted certain documents with his letter of March 4, 2005 including a) minutes of a monthly medical staff meeting which was held on June 25, 2004 and reconvened on July 2, 2004; b) Johnson's undated "opening remarks" at a "quality improvement" meeting held on April 9, 2004; and c) a formal memo printed on GMH letterhead and directed to four physicians and two laypersons informing Costa and others of a medical staff review pursuant to the hospital's "Quality Improvement Process" concerning an "obstetrical case from 4-1-04." (AR 0062-0065) (AR 0072-0074)
- 32. The GMH hospital bylaws provide that routine medical staff meetings are held once a month and all members of the active medical staff at GMH are required to attend the meetings. (AR 0147)
- 33. With regard to the three documents furnished by Johnson on March 4, 2005, with one exception (a referral to a 4/1/04 obstetrical case), Johnson's "opening remarks" do not correspond to the memo issued on April 6, 2004. The memo stated that the meeting was being called for the purpose of reviewing one obstetrical case for quality assurance purposes. (AR 0072) Johnson's opening remarks pertain to miscellaneous other matters, notably three obstetrical cases, a general reminder to all members of the medical staff, and a "request" that Johnson claims (in his opening remarks) he made to the Executive Committee to address alleged concerns relative to three of Costa's obstetrical cases. (AR 0073-0074) Johnson declined to furnish Ms. Brentley with the minutes of the April 9, 2004 quality improvement meeting substituting instead his undated, self-prepared, "opening remarks." (AR 0060)

- 34. Following receipt of GMH's submission of March 4, 2005, Joyce Ann Brentley instructed Johnson to either submit a Correction Report or void the initial report. (AR 0078-0079)
- 35. On April 6, 2005, Johnson filed a Correction Adverse Action Report this time claiming there was a "review" (not an investigation) of Costa occurring at the time he withdrew his application for privileges, and that there were concerns regarding "recent obstetrical cases" and "professionalism" to nursing and administrative staff. The Correction Report states:

Dr. Costa's competence and professionalism were under review at the Gothenburg Memorial Hospital at the time he withdrew his medical staff application for re-appointment and surrendered his privileges. The medical staff had concerns regarding recent obstetrical cases in which Dr. Costa was the primary physician, as well as concerns regarding his professionalism to nursing and administrative staff. Dr. Costa surrendered his privileges one and one half hours after the medical staff unanimously voted to reject his application for reappointment and prior to that recommendation being forwarded to the Board of Directors for further action.

(AR 0088) No additional documentation was ever furnished by Johnson in support of these "corrected" allegations.

- 36. Costa placed the Correction Report in dispute and filed a revised Subject

 Statement in response thereto. He renewed his request for Secretarial Review. (AR 0088-0089)
- 37. The minutes of the reconvened medical staff meeting of July 2, 2004 reflect Johnson's "concerns" regarding Costa and are different than those reflected in Johnson's opening remarks from the April 9, 2004 quality assurance meeting. (AR 0064) (AR 0073-0074)
- 38. Johnson's concerns as reflected in the minutes of the meeting were voiced for the first time at the July 2, 2004 medical staff meeting and not as a part of any formal investigation being conducted or contemplated by GMH. "[Costa] was advised at the June 25, 2004 meeting

that his renewal application for staff privileges would be addressed at the July 2, 2004 meeting. The meeting minutes from July 2, 2004 reflect the concerns regarding Dr. Costa that were raised at that meeting." (AR 0059) (Emphasis supplied.)

- 39. Johnson has never submitted contemporaneous documentation of an investigation by the Executive Committee as defined by GMH bylaws through its formal procedures and processes. (AR 0139-140) Such documentation would necessarily include:
 - a. "A written request for an investigation of the matter . . . addressed to the Executive Committee making specific reference to the activity or conduct which gave rise to the request;" (AR 0139) *and*
 - b. Notes, memoranda, or other documentation generated by the Executive Committee during the course of its investigation; (AR 0139) *or*
 - c. The Executive Committee's summary of its interview with Costa; (AR 0140) or
 - d. The Executive Committee's formal recommendation to the Board following its investigation. (AR 0140)
- 40. In his August 24, 2005 Secretarial Review Decision, the Secretary determined Costa voluntarily surrendered his clinical privileges while under investigation, and that this was a reportable event. (AR 0194)
- 41. In reaching his determination, the Secretary relied upon Johnson's letter of March 4, 2005, with enclosures. (AR 0195)

ARGUMENT

I.

DEFENDANTS' ACTIONS WITH REGARD TO ADVERSE ACTION REPORT

5500000037166652 (CORRECTION REPORT) WERE ARBITRARY, CAPRICIOUS, AN

ABUSE OF DISCRETION, OR OTHERWISE NOT IN ACCORDANCE WITH LAW.

A. There was no "Reportable" Event Which Triggered Johnson's Obligation to File a

Correction Report with the Data Bank.

There are limited circumstances under which a report to the Data Bank is required. The relevant regulations provide that a report by a health care entity relative to physicians is required only for:

Each health care entity which -

- (A) takes a professional review action that adversely affects the clinical privileges of a physician for a period longer than 30 days:
- (B) accepts the surrender of clinical privileges of a physician
 - (i) while the physician is under investigation by the entity relating to possible incompetence or improper professional conduct, or
 - (ii) in return for not conducting such an investigation or proceeding[.]

42 U.S.C. § 11133 (West 1995 and Supp. 2004). Only 42 U.S.C. § 11133(a)(1)(B)(i) is implicated in the present case.

It is clear that GMH is a "health care entity" as defined under the Health Care Quality Improvement Act (HCQIA). A health care entity includes "a hospital that is licensed to provide health care services by the state in which it is located." 42 U.S.C. § 11151(4)(A) (West 1995 and

Supp. 2004). Thus, the only question on appeal is whether the record supports the Secretary's conclusion that Costa was "under investigation" by GMH relating to possible incompetence or improper professional conduct at the time he surrendered his clinical privileges. As the following analysis indicates, there was no "investigation" by GMH and, thus, no reportable event.

- i. Costa did not surrender his staff privileges while under investigation by GMH.
- a. <u>The Secretary's Reliance Upon a Cover Letter as "Contemporaneous" Evidence</u> of an Investigation was an Abuse of Discretion.

The National Practitioner Data Bank Guidebook (NPDB Guidebook) provides some guidelines as to what constitutes an investigation:

- An investigation must be carried out by the health care entity, not an individual on the staff.
- The investigation must be focused on the practitioner in question.
- The investigation must concern the professional competence and/or professional conduct of the practitioner in question.
- A routine or general review of cases is not an investigation.
- A routine review of a particular practitioner is not an investigation.
- An investigation should be the precursor to a professional review action.
- An investigation is considered ongoing until the health care entity's decision making authority takes a final action or formally closes the investigation.

(NPDB Guidebook, at E-19, September 2001) Further, "[a] health care entity that submits an [Adverse Action Report] based on surrender or restriction of a physician's or dentist's privileges

while under investigation should have *contemporaneous* evidence of an ongoing investigation at the time of surrender[.]" Id. (Emphasis supplied.)

One court noted that the National Practitioner Data Bank Guidebook "offers guidance as to what constitutes a surrender of privileges and when a physician is considered 'under investigation.'" <u>Diaz v. Provena Hospitals</u>, 817 N.E.2d 206, 211 (Ill. App. 2004). That court further noted:

[t]he Guidebook is published by HHS and sets forth HHS's interpretation of its own regulations. Consequently, to the extent the Guidebook applies to the facts of this case, it is entitled to substantial deference.

Id. at 211.

The Guidebook indicates exactly what evidence the Secretary requires in order to find that an investigation was under way at the time a physician surrenders privileges.

A health care entity that submits an [Adverse Action Report] based on surrender or restriction of a physician's or dentist's privileges while under investigation should have contemporaneous evidence of an ongoing investigation at the time of surrender, or evidence of a plea bargain. The reporting entity should be able to produce evidence that an investigation was initiated **prior** to the surrender of clinical privileges by a practitioner. *Examples of acceptable evidence may include minutes or excerpts from committee meetings, orders from hospital officials directing an investigation, and notices to practitioners of an investigation.*

(NPDB Guidebook, at E-19) (Emphasis in bold in original. Emphasis in italics supplied.)

In the case at bar, the Secretary relied upon four documents submitted by Johnson in reaching the conclusion that Costa was under investigation when he voluntarily surrendered his privileges. One of those "documents" was Johnson's March 4, 2005 cover letter to the Secretary enclosing three other documents. (AR 0059-0061) The Secretary stated:

John Johnson, CEO of GMH sent to our office a letter of March 4, 2005 with enclosures supporting GMH's claim that an investigation was in process.

. . . .

Moreover, Mr. Johnson states in his above-referenced March 4, 2005 letter that:

"... I decided that those meeting minutes were relevant to your determination in that they set forth the *culmination of the investigation* which resulted in the medical staff voting to reject Dr. Costa's application for renewal of staff privileges."

(AR 0195) (Emphasis in Secretarial Review Decision.) To the extent the Secretary relied upon Johnson's unsubstantiated statements in a cover letter as contemporaneous documentation of an investigation, such reliance was entirely misplaced. GMH bylaws mandate that if an investigation is initiated "a written request" to the Executive Committee shall be made "making specific reference to the activity or conduct which gave rise to the request." (AR 0139) The bylaws also require the Executive Committee to make a formal recommendation to the board following an investigation. (AR 0140) If, in fact, the minutes submitted by Johnson set forth the "culmination of an investigation," then the written request to the Executive Committee which made specific reference to the activity or conduct in question and the Executive Committee's formal recommendation to the Board would have been readily available and easily produced by Johnson. Johnson's unsworn personal opinions and characterizations as set forth in his cover letter to the Secretary are not a substitute for contemporaneous evidence. The Secretary acknowledged that a health care entity that submits an Adverse Action Report based on surrender or restriction of a physician's privileges while under investigation must submit contemporaneous evidence of an ongoing investigation at the time of surrender. (AR 0196) On its face, the letter

of March 4, 2005 shows it was authored by Johnson long after the events set forth in the Adverse Action Report and is not a contemporaneous document related to an investigation. The letter is nothing more than Johnson's recitation of undocumented events, references to documents which supposedly exist but were withheld, and his own interpretation of those alleged events and documents. Any reliance by the Secretary on statements made in Johnson's March 4, 2005 cover letter which were not supported with contemporaneous evidence was arbitrary and capricious and constitutes an abuse of discretion.

b. <u>An investigation must be conducted by a health care entity, not an individual on the staff.</u>

An investigation must be conducted by a health care entity, not an individual on the staff. (NPDB Guidebook, at E-19) The court in Joshi v. St. Luke's Episcopal-Presbyterian Hospital, 142 S.W.3d 862, 868 (E.D. Mo. 2004) dealt with this particular issue. In that case, the physician claimed that the head of the anesthesiology department acted alone in suspending his privileges. Thus, he claimed, the actions of one department chief did not constitute an "investigation." The court ruled otherwise, finding that the evidence reflected an investigation which included an outside evaluation of the physician's competency and action taken by the hospital's Executive Committee in upholding the suspension. In so ruling, the court looked to contemporaneous evidence of an ongoing investigation by various individuals and committees. Thus, an "investigation" by a health care entity should be evidenced by the involvement of designated individuals or committees and contemporaneous documentation thereof. Joshi, supra. See also NPDB Guidebook, at E-19 (contemporaneous evidence required).

While the NPDB Guidebook does not set forth a standard procedure for instituting and conducting investigations, it clearly reflects the intent that investigations will be of such a formal nature that unequivocal, documentary evidence of the investigation can readily be produced by health care entities. In this case, if the investigative procedure set forth in GMH's bylaws had been followed, GMH would have been able to readily produce to the Secretary such contemporaneous evidence. Again, the bylaws require that "a written request" for an investigation be made to the Executive Committee "making specific reference to the activity or conduct which gave rise to the request." (AR 0139) Additionally, the bylaws require the Executive Committee to make its recommendations to the board following an investigation. (AR 0140) Thus, in order for the Executive Committee to commence an investigation of a physician, it must first receive a written request outlining the activity or conduct giving rise to the request. It would have been a simple matter for GMH to submit to the Secretary the written request to the Executive Committee. Thus, it can be concluded that such a request was never made. Johnson did not submit to the Secretary a written request, i.e. "contemporaneous evidence," to the Executive Committee for an investigation of Costa. Instead, he submitted undated, self-prepared opening remarks and minutes of a medical staff meeting which outline *Johnson's* "concerns" about matters largely, if not entirely, unrelated to the allegations in the Correction Report. He also submitted the cover letter he authored as discussed above and the memo notifying staff of the April 6, 2004 quality assurance meeting. (AR 0059-0074) The documentation submitted by Johnson was no substitute for what should have been readily available contemporaneous evidence. The fact that Johnson could not produce the one document GMH requires in order to initiate an investigation against a physician leads to only one conclusion - there was no

investigation. Further, to the extent the documents submitted by Johnson indicate *he* had concerns about Costa, such documents are irrelevant to the issue of whether an investigation was being conducted. An investigation must be conducted by a health care entity, not an individual employed on the staff. (NPDB Guidebook, at E-19); <u>Joshi</u>, supra.

c. A routine review of a particular practitioner is not an investigation.

A routine review associated with the renewal of privileges should not be confused with an "investigation." In the instant case, Johnson merely alleged in the Correction Report that Costa was under "review" at the time he withdrew his application for renewal of clinical privileges. Specifically, Johnson stated:

Dr. Costa's competence and professionalism were under review at the Gothenburg Memorial Hospital at the time he withdrew his medical staff application for re-appointment and surrendered his privileges.

(AR 0088) Johnson did not state that Costa was under investigation at the time he surrendered his privileges. The NPDB Guidebook is very clear—routine reviews are not investigations. See NPDB Guidebook, at E-19 ("A routine or general review of cases is not an investigation. . . A routine review of a particular practitioner is not an investigation. . . An investigation should be the precursor to a professional review action."). The "review" being conducted at the time Costa surrendered his privileges was clearly a routine review—one the hospital is required to complete for every physician who applies, or reapplies, for clinical privileges. The bylaws of the hospital mandate such a routine review. (AR 0132-0135)

In addition to the plain language of the Guidebook, various courts have been called upon to determine whether a physician was under "investigation" for purposes of Data Bank reporting in a variety of factual scenarios. In some cases, the investigations are so obvious that the court's

review is cursory. For example, see Brader v. Allegheny General Hospital, 167 F.3d 832, 836 (3rd Cir. 1999) (whether there was an investigation was not questioned when a review of a certain procedure identified an excessive number of adverse outcomes for patients of the plaintiff, where such review was followed up by a review of the plaintiff by the Director of the Division of General Surgery and also by an independent expert); Austin v. McNamara, 979 F.2d 728, 731-32 (9th Cir. 1992) (in response to complaints, the chief of staff determined an internal evaluation of plaintiff's cases was necessary in over 30 cases, an independent expert was hired to review plaintiff's cases, the plaintiff was subject to a monitoring system, and a special ad hoc committee was formed by the Medical Executive Committee in order to investigate the plaintiff); Singh v. Blue Cross and Blue Shield of Massachusetts, Inc., 182 F. Supp. 2d 164, 168-72 (D. Mass. 2001) ("the massive investigation" consisted of an audit of a random sample of 25 of the plaintiff's files by an independent expert, the involvement of several committees in fact-finding, and a second audit by an independent expert of 37 files of patients of the plaintiff); Fobbs v. Holy Cross Health System Corp., 789 F. Supp. 1054, 1057-58 (E.D. Cal. 1992) (investigation not questioned where three different hospital committees reviewed plaintiff's cases, a monitoring system was imposed, and plaintiff appealed the decision of the credentialing committee).

One court, finding that a physician's knowledge of an investigation was extremely important in an inquiry as to whether the physician surrendered his privileges while under investigation, discussed the nature, knowledge and contemporaneous documentation of an investigation at length. In <u>Lee v. Hospital Authority of Colquitt County</u>, 353 F. Supp. 2d 1255 (M.D. Ga. 2004), the court stated:

... Dr. Lee contends that he did not receive notice of the investigation of his application for reappointment or of his surgical

complications. In addition to the memoranda [regarding subject matter of meetings with Dr. Lee], however, there is substantial undisputed evidence to indicate that Dr. Lee was actually aware of the investigation and of the nature of the committee's concerns. As noted above, he received written notice from Dr. Adcock that the matter of his application responses would be brought to the attention of the Medical Executive Committee. He also received the April 20, 2001 letter from Dr. Lamon regarding the postponement of his application for reappointment and requesting a meeting. Furthermore, members of the ad-hoc committee have testified that Dr. Lee discussed the investigation with them personally. Dr. Melton has testified that Dr. Lee approached him in the surgery lounge and asked him why the committee was looking into his record of complications in surgical cases, and that he had a similar discussion concerning the ad-hoc committee's work on a second occasion, shortly before Dr. Lee's resignation from the staff. Dr. Lamon has testified that Dr. Lee approached him and reviewed his conversation with Dr. Melton. In that conversation with Dr. Lamon, Dr. Lee expressed concern that the investigation was threatening his livelihood.

Id. at 1259.

In stark contrast to the above cases, no such knowledge or contemporaneous evidence of an investigation exists in the present case. First, Johnson made only two claims in the Correction Report: "The medical staff had concerns regarding recent obstetrical cases in which Dr. Costa was the primary physician, as well as concerns regarding his professionalism to nursing and administrative staff." (AR 0088) Thus, any contemporaneous documentation of an investigation would necessarily have to pertain to these two "concerns" and would have to be reflective of an actual investigation, as opposed to a routine review, and one which was being conducted by GMH, not merely an individual on staff.

Johnson submitted to the Secretary three documents relating to two different meetings in support of his contention that Costa was under investigation at the time of surrender. Those two meetings are the "quality improvement" meeting of April 6, 2004 and the medical staff meeting

of June 25, 2004 which reconvened on July 2, 2004. In relation to the quality improvement meeting, Johnson submitted a memo which was sent to various individuals, as well as his own informal, undated opening remarks which he claims he made at the meeting. (AR 0072-0074) In relation to the medical staff meeting, Johnson submitted the minutes from June 25, 2004 and July 2, 2004. (AR 0062-0065)

The minutes from the June 25, 2004 meeting contain no references to any ongoing or impending investigations. The minutes of the reconvened July 2, 2004 medical staff meeting reflect that "*Mr. Johnson* voiced numerous concerns" and specifically identified the following "concerns" regarding Costa:

- 1. Dr. Costa failing to supervise his PA;
- 2. PA refusing to take ER call but wanting to remain on active medical staff;
- 3. Dr. Costa requesting a status for PA that did not exist in the medical staff bylaws;
- 4. Dr. Costa failing to intervene or attempt to correct situations in which his PA was argumentative and verbally abusive to hospital staff members;
- 5. Dr. Costa allowing his PA to engage in activities outside her scope of practice:
 - a. Stripping membranes in office setting;
 - b. Giving TNKase in ER with no supervising physician in attendance;
 - c. Allowing PA to deliver babies, perform (sic) third and forth (sic) degree perineal tears and lacerations and pull umbilical cord apart.
- 6. Dr. Costa accused the hospital and staff of a shameful decline in the quality of care being provided;
- 7. Dr. Costa in a letter to the editor, referred to the Administrator as a "tin horn";
- 8. In a sworn statement indicated that the Board of Directors had "utterly failed" in their responsibility to oversee the administrator of the facility;
- 9. Accused the hospital of overcharging for copies of documents (unfounded);
- 10. Accused the hospital Board of having secret, illegal meetings (unfounded):
- 11. Alleged violation of HIPPA (sic) privacy issue and signed (OHCA) Organizational Health Care Arrangement.

(AR 0064) One sentence in the July 2, 2004 minutes provides: "Medical Staff agreed with and voiced numerous other concerns." (AR 0064) It is unknown what those concerns were and there is no indication there was ever an investigation relative to the concerns voiced by Johnson on July 2, 2004. Johnson did not submit to the Secretary any written requests to the Executive Committee for an investigation of Johnson's alleged concerns, and the concerns expressed on July 2, 2004 do not correlate to the obstetrical cases reviewed on April 9, 2004 at the quality improvement meeting. These facts are significant. Where is the contemporaneous documentation of an investigation? Where are the written requests to the Executive Committee? Under its own bylaws, this is the mandatory starting point for any investigation of a physician. (AR 0139) The fact that Johnson could not produce such documentation, and instead produced documentation showing only his personal opinions (opening remarks) and personal concerns (his list of complaints set forth in the July 2, 2004 minutes), leads to the conclusion that there was no investigation of Costa at the time he surrendered his privileges. Johnson claimed, and the Secretary agreed, that the quality improvement meeting held on April 9, 2004 was evidence of an investigation. (AR 0060) (AR 0195) In support of his decision that Costa was being investigated, the Secretary stated: "Specifically, there is a note with a facsimile date of 'Apr 09 04 08:49 am' detailing pending deliberations of the Executive Committee." (AR 0195) The "note" referenced by the Secretary is not a document generated by the Executive Committee during the course of an investigation. It is Johnson's self-prepared opening remarks at a quality improvement meeting. This is the same meeting for which he refused to submit the minutes or actual taped recording to the Secretary. "Due to the confidentiality of Quality Assurance meetings, I am not providing a copy of the minutes of this meeting. . ." (AR 0060) Yet, Johnson readily produced

other confidential minutes when it suited his purposes. "In my December 27, 2004 correspondence, I did not provide you with a copy of the medical staff minutes due to their privileged nature. In light of Ms. Rasmussen's correspondence, however, I decided that those meeting minutes were relevant to your determination . . . I have obtained the written consent of the remaining active staff members and have enclosed a copy of the minutes of June 25, 2004 and July 2, 2004 medical staff meetings." (AR 0059) If, in fact, there were "pending deliberations" by the Executive Committee, as determined by the Secretary, then there would be contemporaneous documentation as outlined in GMH's bylaws and not simply documents reflecting *Johnson's* opening remarks and his laundry list of concerns. Johnson is not authorized under the bylaws to unilaterally or individually conduct an investigation on behalf of the hospital. If he desires an investigation, the bylaws provide the procedure to be followed and identify the documentation to be generated. Simply put, Johnson's "opening remarks" and "concerns" do not constitute an investigation by GMH, under either the GMH bylaws or the Data Bank Guidelines.

Of the "concerns," stated by Johnson in the July 2, 2004 minutes, items 2, 3, 4 and 11 are not related in any way to the two allegations reflected in the Correction Report ("recent obstetrical cases in which Dr. Costa was the primary physician" and "concerns regarding his professionalism to nursing and administrative staff." (AR 0088) The remaining "concerns" are addressed below.

Obstetrical "Concerns"

a. Medical Staff Meeting

In the Correction Report, Johnson claims: "The medical staff had concerns regarding recent obstetrical cases in which Dr. Costa was the primary physician. . . " (AR 088) Yet, in looking at Johnson's listed concerns, it is apparent that the only concerns which might bear on Johnson's claim in the Correction Report regarding "recent obstetrical cases" are item 1 (possibly) and item 5 (possibly). It is unclear exactly what item No. 1 relates to as it is stated as a general concern. However, at the time of the July 2, 2004 medical staff meeting, Costa's PA had not provided medical services at GMH for over a year. (AR 0123) Thus, this item could not have pertained to "recent obstetrical cases" in which Costa was the primary physician. Those obstetrical cases were the three cases noted in Johnson's opening remarks and occurred after Costa's PA ceased providing services at the hospital. (AR 0073) In addition, the "concerns" outlined in item 5 pertain to the claimed medical practices of the PA, not the medical practices of Costa, and item (a) pertains to a medical procedure which occurred somewhere other than GMH, ("stripping membranes in office setting"). Again, the PA has not practiced medicine at GMH since at least July 1, 2003. (AR 0123) Thus, as of July 2, 2004 these concerns could not have been related to any of Costa's "recent obstetrical cases." More significantly, however, the National Practitioner Data Bank Guidebook provides that an "investigation must be focused on the practitioner in question," (not his PA), and "the investigation must concern the professional competence and/or professional conduct of the practitioner in question," (not his PA). NPDB Guidebook, at E-19 September 2001. Thus, to the extent any "obstetrical concerns" were voiced at the July 2, 2004 medical staff meeting by Johnson, they were concerns related to the medical practices of a health care practitioner other than Costa; were not related to recent obstetrical cases where Costa was the primary physician; and were related to events outside the confines of

the hospital. The Secretary appears to acknowledge this in one breath, yet disregard it in the next. "Although some of the allegations at issue do not concern your professional conduct or professional competence, the July 2, 2004 minutes are evidence of an investigation of your clinical practice activity in keeping with the Guidebook requirements. . ." (AR 0196)

With the exception of the items discussed above, there were no other items of concern expressed at the July 2, 2004 medical staff meeting regarding obstetric care. The documentation from the July 2, 2004 medical staff meeting does not constitute contemporaneous evidence of any investigation at all, particularly one relative to any of Costa's recent obstetrical cases. The documentation from the July 2, 2004 medical staff meeting does not reflect an investigation by a "health care entity" but rather reflects the statements of a chagrined administrator. "Mr. Johnson voiced numerous concerns . . . " (AR 0064) The documentation from the July 2, 2004 medical staff meeting does not reflect compliance with the hospital's bylaws concerning investigations of physicians. Article IV, Section 5 requires a written request to the Executive Committee and an investigation by such *committee*. (AR 0138-0141) (AR 0146) One hospital administrator voicing "concerns" at a monthly medical staff meeting does not equate to an investigation which comports with the hospital's investigative process and procedures. Further, none of the concerns voiced by Johnson on July 2, 2004 pertain to the obstetrical case or cases reviewed at the quality improvement meeting on April 9, 2004. (It was one case according to the memo from the Chief of Staff; three cases according to Johnson's opening remarks; yet Johnson also stated to the Secretary "The meeting was called to review *an* obstetrical case of Dr. Costa's.") (AR 0060) (AR 0072-0074) There is no indication in the July 2, 2004 minutes that one or more obstetrical cases were being investigated, and there is no documentation that the review of April 9, 2004

was anything other than a routine quality improvement meeting called to review an obstetrical case in which complications arose.

b. Quality Improvement Meeting

On April 6, 2004, four physicians and two lay persons were given notice by the Chief of Staff that a quality assurance meeting would take place on April 9, 2004 to review an obstetrical case of April 1, 2004. (AR 0072) The memo refers to one obstetrical case and states "This is meant to be a Quality Improvement Process and I appreciate your cooperation." (AR 0072) Clearly, this was a routine review for quality improvement purposes and nothing more. In support of his claim that this meeting constituted an investigation of Costa, Johnson submitted his own opening remarks which he claims to have made at the beginning of this meeting. The Secretary found these opening remarks to be evidence of an investigation. (AR 0195) Johnson's personal comments, opinions and concerns, stated at the beginning of a meeting do not transform a routine quality improvement meeting into an "investigation." This is particularly true where Johnson declined to furnish the Secretary with the minutes from this meeting. It is significant that when Johnson's claimed "concerns" were outlined in the minutes of the July 2, 2004 medical staff meeting, the minutes were devoid of any concerns regarding Costa's clinical judgment or patient care, and no concerns were raised regarding the obstetrical case reviewed on April 1, 2004. (AR 0062-0065) This supports Costa's position that the April 9, 2004 review of one obstetrical case was just what it purported to be in the memo issued by the Chief of Staff, a routine quality improvement meeting. (AR 0072) No documentation was submitted by Johnson to indicate that there was an ongoing investigation concerning the obstetrical case, or even that there were any remaining concerns following the review of the case on April 9, 2004.

Keeping in mind that GMH, as opposed to an individual on staff, must conduct an investigation, that such an investigation must focus on the practitioner in question, and that such investigation must be evidenced by unequivocal, contemporaneous documentation, it is clear that GMH was not conducting an investigation of Costa at the time he surrendered his privileges.

Johnson was unable to produce what should have been readily available contemporaneous documentation. Further, Costa was never notified of an investigation and was never offered an opportunity to meet with the Executive Committee concerning an investigation. (AR 0050) The bylaws provide: "The individual with respect to whom an investigation has been requested shall have an opportunity to meet with the Executive Committee before it makes its report. . . . The Executive Committee shall make a summary of such interview." (AR 0139-0140) Johnson produced no documentation of a notice to Costa or a summary prepared by the Executive Committee.

Finally, one of the documents relied upon by the Secretary in support of his ruling, was a memo calling for the April 9, 2004 quality improvement meeting. The memo was issued by Craig Bartruff, M.D., the Chief of Staff at GMH (Bartruff). (AR 0072) On July 12, 2004, just ten days after Costa surrendered his privileges and prior to Johnson filing the first Adverse Action Report, Bartruff submitted a statement on Costa's behalf to the Nevada State Board of Medical Examiners. (AR 0011) In that statement, Bartruff confirmed that Costa's staff privileges had never been limited, restricted, suspended or revoked, and that there was no derogatory information concerning Costa on file with GMH. (AR 0011) On July 26, 2004, five days after Johnson filed the first Adverse Action Report, Bartruff again confirmed to the Nevada State Board of Medical Examiners that Costa's staff privileges had never been limited, restricted,

suspended or revoked, and that there was no derogatory information concerning Costa on file with GMH. (AR 0012) Bartruff had first-hand knowledge of the memo he issued on April 6, 2004, the quality improvement meeting he attended on April 9, 2004, and the medical staff meetings he attended on June 25, 2004 and July 2, 2004. His written statements to the Nevada State Board of Medical Examiners clearly and unequivocally refute Johnson's contention that the April 9, 2004 meeting and/or the July 2, 2004 meeting reflect an "investigation" of Costa. The Chief of Staff is a designated member of the Executive Committee and would have been well aware of any "investigation" of Costa. (AR 0146) The Secretary did not discuss the statements of Bartruff in his Secretarial Review Decision, and the failure to consider this evidence was an abuse of discretion. Similarly, the Secretary's finding that Costa was under investigation for recent obstetrical cases at the time of surrender is not supported by the evidence and is arbitrary, capricious and an abuse of discretion.

"Professionalism"

The second claim made by Johnson in the Correction Report is that there were "concerns regarding [Costa's] professionalism to nursing and administrative staff." (AR 0088) It is not entirely clear that this claim, as stated, even constitutes a reportable event. The NPDB Guidebook provides "The investigation must concern the *professional competence* and/or *professional conduct* of the practitioner in question." (NPDB Guidebook at E-19, September 2001) Thus, in order to be reportable the event must relate to the medical competence or conduct of the practitioner.

Johnson has not demonstrated through the production of contemporaneous documentation that Costa's claimed lack of "professionalism" is related to his medical

competence or conduct. In fact, the only document Johnson produced which might bear on this claim are the minutes from the reconvened July 2, 2004 medical staff meeting. (AR 0064-0065) Those minutes make it abundantly clear that what Johnson considers a lack of "professionalism" is really nothing more than Costa's statements on two recall petitions and a letter to the editor of a local paper. In fact, the minutes of the medical staff meeting of July 2, 2004 quote the language from the recall petitions and the letter to the editor. (AR 012-0122) None of this has any bearing on Costa's professional competence or conduct. Costa's public statements pertaining to matters of public concern cannot be the basis for an Adverse Action Report. The Secretary does not address the "professionalism" allegation in his Secretarial Review Decision. The Secretary does not point to any evidence which supports the allegation in the Correction Report that Costa was under investigation for "concerns regarding [Costa's] professionalism to nursing and administrative staff" at the time of surrender. The Correction Report limited the allegations against Costa to: concerns regarding recent obstetrical cases, and concerns regarding professionalism to nursing and administrative staff. (AR 0088) Costa challenged, among other things, the factual accuracy of the Correction Report and placed it in disputed status. (AR 0103-0104) Costa produced evidence from the Chief of Staff of GMH that there was no derogatory information concerning him on file with GMH. (AR 0011-0012) When Johnson failed to produce contemporaneous documentation of an investigation concerning Costa's claimed lack of professionalism to nursing and administrative staff, the Secretary should have ordered that the Correction Report be voided or corrected, in whole or in part. The failure to do so was an abuse of discretion.

Johnson's concerns voiced at the July 2, 2004 medical staff meeting pertaining to Costa's public statements (which constitute protected free speech and are unrelated to patient care or medical competency) do not constitute an "investigation" for Data Bank purposes. Clearly, Costa has been outspoken in his opinions on the current administration of the hospital and has taken legal and legitimate means to alter the current makeup of the administration. However, neither his public efforts nor his public statements made during the course of the local election process constitute a lack of "professionalism to nursing and administrative staff" merely because he stated his opinions about deficiencies at the hospital on the recall petitions as required by law. Further, a lack of "professionalism" as this term is used by Johnson is not reportable to the Data Bank. In a case strikingly similar to the case at hand, a physician working at the Laguna Honda Hospital learned that for budgetary reasons the hospital was laying off physicians who were nearing retirement age. Ulrich v. City & County of San Francisco, 308 F.3d 968 (9th Cir. 2002). He protested the lay-offs at a staff meeting claiming they were "an injustice to the patients" by diminishing physician-to-patient ratios. Id. The following week, he sent a letter of protest to two officials at the San Francisco Department of Health questioning the ability of medical staff to care adequately for its patients in light of the layoffs. Id. The physician was subsequently notified that the hospital was investigating him for "professional incompetence" and the physician resigned from the hospital staff. Id. Thereafter, the hospital filed an adverse action report with the Data Bank claiming the physician surrendered privileges while under, or to avoid, investigation. The Data Bank refused to void the report. Id. The physician filed suit against the hospital claiming, inter alia, that the disciplinary investigation of him was intended as

punishment for speech protected by the First Amendment. <u>Id</u>. The Ninth Circuit U.S. Court of Appeals held:

Dr. Ulrich was subjected to more than trivial adverse employment actions. The hospital subjected him to an investigation that threatened to revoke his clinical privileges. It subsequently refused to rescind his resignation and filed an adverse action report against him, marring his employment record. Although these decisions by the hospital could have been taken for a number of reasons, if they were in retaliation for his protected speech activity then the First Amendment was violated. . . . When speech addresses 'issues about which information is needed or appropriate to enable the members of society to make informed decisions about the operation of their government,' it 'falls squarely within the boundaries of public concern'.... Dr. Ulrich's protests of the layoff of physicians touched on the ability of the hospital to care adequately for patients, sparking debate about whether there were less harmful ways to address the hospital's budgetary problems. There is clear 'public import in evaluating the performance' of a public agency to assess the 'efficient performance of its duties.'...[T]here is direct evidence that Dr. Ulrich's speech was a motivating factor in Dr. Rivero's decisions regarding Dr. Ulrich. . . . [A]ll of the adverse actions about which Dr. Ulrich complains came close on the heels of his protected speech activity. [Dr. Rivero] made the decision to file an adverse action report about Dr. Ulrich to state and federal authorities five days after the effective date of Dr. Ulrich's resignation and a little over a month after his resignation notice was posted. The proximity in time between each of these adverse actions and Dr. Ulrich's speech is well within time frames we have held sufficient for a jury to infer discriminatory motive. See Allen, 283 F.3d at 1078 (holding that an 11-month gap in time between the protected speech and denial of a government benefit "is within the range that has been found to support an inference than an employment decision was retaliatory"). . . . Finally, Dr. Ulrich has presented evidence from which a jury could conclude that Dr. Rivero's stated reason for filing an adverse action report against him was false and pretextual. . . . Indeed, Dr. Ulrich has pointed to minutes from a Committee meeting in early October indicating the Committee decided to conclude its investigation without speaking to him. A jury could find from these facts that Dr. Rivero's assertion that she was required to file an adverse action report against Dr. Ulrich because an investigation was pending on November 1 was false and pretextual.

Id. 308 F.3d 968, 977-980.

While the Secretary's review is limited by law to a determination of whether the Correction Report is accurate and whether it sets forth a reportable event, the foregoing case is

certainly enlightening in terms of what does *not* constitute a reportable event. In this case, Costa made public statements advocating for changes he felt were needed at the hospital. The recall petitions were filed January 5, 2004. (AR 0120-0121) On March 15, 2004 the local newspaper published Costa's letter protesting the termination of a GMH nurse anesthetist and stating the nurse anesthetist "has done more for this community - is worth more - than one thousand tinhorn hospital administrators." (AR 0122) Four months later during the July 2, 2004 medical staff meeting, Costa's public statements were set forth in the minutes as "alleged concerns" of Johnson's. (AR 0064) The timing and sequence of these events cannot be ignored. Significantly, Costa produced the minutes of the July 15, 2004 district hospital board meeting which reveal that the hospital board was not aware of any investigation involving Costa and did not see a need to file an Adverse Action Report with the Data Bank:

The Board also discussed the withdrawal of application and *voluntary* surrender of privileges from Dr. Costa. Brent Block motioned to accept the withdrawal of Dr. Costa's application and the *voluntary* surrender of privileges. Kathi Viergutz seconded and the motion carried unanimously.

Mike Bacon requested that the minutes reflect that the Hospital Board has taken no action or had direct communication with Dr. Costa. The only communication has been the withdrawal of Dr. Costa's application.

. . .

Monty Bowman questioned if anything further will need to be done by the Hospital. The administration will have to report *to the state* that Dr. Costa withdrew his application and *voluntarily* surrendered his privileges.

(AR 0015-0017)

While GMH may or may not be required to notify the Nebraska Department of Health and Human Services whenever a physician withdraws an application for privileges, or voluntarily surrenders privileges, federal law does not require a report to the Data Bank unless

the physician surrenders privileges while under investigation or to avoid an investigation. The minutes of the July 15, 2004 hospital board meeting indicate that no investigation was occurring, no investigation was impending and no report to the Data Bank was contemplated. While the Secretary was not allowed to address Johnson's motive in filing the Adverse Action Report, and then the Correction Report, it is hard to overlook the striking similarities between this case and the <u>Ulrich</u> case. The minutes of the district hospital board meeting clearly indicate the board saw no need to file an Adverse Action Report with the Data Bank.

B. The Hospital's Failure to Follow its Own Investigative Procedures as Set Forth in the Bylaws Supports Costa's Contention that no Investigation was ever Conducted.

The GMH bylaws dictate exactly how an investigation is to occur. Investigations at GMH do not occur during the exchange of educational information, opinions and concerns at monthly medical staff meetings, or at routine quality improvement meetings. They occur through the investigative process and procedures outlined in the bylaws and are evidenced by unequivocal, contemporaneous documentation at each stage of that process. The mere "concerns" of an entity, or an individual on staff at the entity, do not equate to an "investigation" so as to qualify as a reportable incident. See <u>District of Columbia v. Simpkins</u>, 720 A.2d 894, 896-98 (D.C. App. 1998) (despite memoranda exchanged between supervisors regarding concerns about plaintiff's clinical judgment and competence, "even if Dr. Simpkins was under investigation, as matters stand, we cannot determine from the record the point at which the correspondence between Dr. Anderson and Dr. Jean-Jacques became a *formal investigation* of Dr. Simpkins.") Health care entities (GMH included) have legitimate reasons for implementing formal investigatory procedures to be followed when concerns rise to the level where an

investigation into the clinical judgment and competence of a physician becomes warranted, and physicians have legitimate expectations that those procedures will be followed. Courts have been quick to hold hospitals to their own standards as set forth in hospital bylaws in determining whether a physician was "under investigation." In Simpkins v. Shalala, 999 F. Supp. 106 (D.D.C. 1998), the court noted that "[n]either the statute nor the regulations promulgated in furtherance of the HCQI Act define an investigation." Id. at 115. However, the court found the hospital's failure to follow the formal "Complaint Procedure" detailed in the hospital bylaws for conducting an investigation of a physician's incompetency or misconduct was determinative. Id. Such procedure required (1) the complaint to be in writing, signed by the person making the complaint, and submitted to another staff member, (2) that such complaint be submitted to the Medical Director, (3) that the Medical Director personally deliver a copy of the complaint to the accused staff member within a certain amount of time, and (4) that the Medical Director appoint an investigative committee according to particular guidelines. Id. at 115-16. The court noted:

[t]he "review" of Dr. Simpkins did not follow this D.C. General procedure. *D.C. General provided no documentation to HHS that a complaint of any kind was ever submitted to the Medical Director of D.C. General.* As a result, the specified investigatory procedures mandated by D.C. General's Bylaws were never initiated. No complaint was delivered to the accused staff member, Dr. Simpkins, nor was "an investigation committee" appointed as required by the Bylaws. *These deviations from the Bylaws were not minor but rather fundamental in nature and indicate that these actions cannot be reasonably found to constitute an investigation by D.C. General.*

<u>Id</u>. at 116. (Emphasis supplied.) The same observations made by the <u>Simpkins</u> court could be made in the case at bar. A hospital administrator cannot merely voice "concerns" at a monthly medical staff meeting pertaining to issues unrelated to the physician's clinical judgment or

competence and call it an investigation so as to justify a Data Bank report, particularly where such a contention is refuted by the hospital's own Chief of Staff and board of directors.

Johnson suggested to the Secretary that GMH not be held to the investigative standards set forth in its own bylaws, and instead proposed a simplistic and breathtakingly broad interpretation of what constitutes an investigation. (AR 0061) However, under the HCQIA, the word "investigation" is clearly a term of art. "Concerns" are not investigations. To equate the two terms would be to contradict the requirements of the HCQIA. This issue has been of such importance that the NPDB Guidebook specifically addresses what constitutes an investigation under the HCQIA. These standards have already been set out and discussed above and will not be repeated here.

Further, GMH has a clearly defined set of standards regarding how an "investigation" is to be conducted. GMH bylaws provide:

The following shall apply to all Medical Staff members and persons with clinical privileges at the Hospital.

- A. <u>Grounds for Disciplinary Action</u>. Whenever, on the basis of information and belief, *the Chief of the Medical Staff, CEO, or the Chairperson of the Board*, has cause to question
 - (1) the competence of any person with clinical privileges;
 - (2) the care or treatment of a patient or patients or management of a case by any person with clinical privileges;
 - (3) the known or suspected violation by any person with clinical privileges or applicable ethical standards or the bylaws, policies, rules or regulations of the Hospital or its Board or Medical Staff, or
 - (4) behavior or conduct on the part of any person with clinical privileges which is considered lower than the standards of the Hospital or disruptive of the

orderly operation of the hospital or its Medical Staff, including the inability of the individual to work harmoniously with others;

A written request for an investigation of the matter shall be addressed to the Executive Committee making specific reference to the activity or conduct which gave rise to the request.

- B. <u>Investigative Procedure.</u> The Executive Committee shall meet as soon after receiving the request as practicable and if, in the opinion of the Executive Committee:
 - (1) the request for investigation contains information sufficient to warrant a recommendation, the Executive Committee, at its discretion, shall make such a recommendation, with or without a personal interview with the individual whose behavior is in question; or
 - the request for investigation does not at that point contain information sufficient to warrant a recommendation, the Executive Committee shall immediately investigate the matter.
 - i. The Executive Committee shall have available to it the full resources of the Medical Staff and the Hospital to aid in their work, as well as the authority to use outside consultants as required. The committee may also require a physical and mental examination of the individual by a physician or physicians satisfactory to the committee and shall require that the results of such examination to be made available for the committee's consideration;
 - ii. The individual with respect to whom an investigation has been requested shall have an opportunity to meet with the Executive Committee before it makes its report. At this meeting (but not, as a matter of right, in advance of it) the individual shall be informed of the general nature of the evidence supporting the investigation requested and shall be invited to discuss, explain, or refute it. This interview shall not constitute a hearing, and none of the procedural rules provided in this policy with

respect to hearings shall apply. The Executive Committee shall make a summary of such interview.

iii. The Executive Committee shall make its recommendations to the Board for its determination.

(AR -138-0140)

Significantly,

- Johnson has not provided evidence that a written request for an investigation was ever received by the Executive Committee.
- Johnson has not provided evidence that the Executive Committee ever conducted a
 meeting to discuss any such written request.
- Johnson has not provided evidence that the Executive Committee utilized the services
 of an independent consultant in evaluating Costa's competence.
- Johnson has not provided evidence that the Executive Committee ever interviewed
 Costa to discuss an investigation before the Executive Committee made its final report.
- Johnson has not provided evidence that the Executive Committee ever submitted a report or recommendation to the hospital board.

Conspicuously absent in this case is any documentation tied to the investigative process which is specifically and meticulously detailed in the hospital bylaws. A physician has a right to expect that hospital bylaws will be followed by the entity that promulgated them. The court in Burney v. East Alabama Medical Center, 939 F. Supp. 1514, 1526 (M.D. Ala. 1996) held that in order to qualify as a reasonable investigation under HCQIA,

where the investigation includes both prospective and retrospective conduct, the investigation must be reasonable not only in the sense it should be thorough, but also in the sense that it should be fair. It would be unfair, and thus not reasonable, to subject a physician to prospective review under a set of rules different from those he was told would govern his future conduct.

Costa had a right to expect that if he were under investigation by GMH, then GMH would utilize the investigative process set forth in its own bylaws and would the maintain the contemporaneous documentation required by the bylaws. Thus, it was an abuse of discretion for the Secretary not to require Johnson to produce contemporaneous documentation generated from that process in support of the two allegations set forth in the Correction Report. In the absence of such documentation, the Secretary's failure to void or correct the Correction Report, in whole or in part, was arbitrary and capricious, was an abuse of discretion, and was not in accordance with law.

II.

COSTA DID NOT SURRENDER HIS STAFF PRIVILEGES IN ORDER TO AVOID AN INVESTIGATION.

The classification code used by Johnson to identify the type of Correction Report being filed was 1635, "Voluntary Surrender of Clinical Privilege(s), While Under, or to Avoid, Investigation Relating to Professional Competence or Conduct." (AR 0088) However, Johnson does not allege in the Correction Report that Costa surrendered his privileges in order to avoid an investigation, and the Secretary made no finding that Costa had surrendered his privileges in order to avoid an investigation. "The record reflects that you voluntarily surrendered your clinical privilege(s), while under investigation." (AR 0088) (AR 0194) There being no claim in the Correction Report that Costa surrendered privileges in order to avoid an investigation, and

there being no findings to that effect by the Secretary, this issue will not be briefed by Costa unless it is raised in defendants' motion for summary judgment or brief in support thereof.

CONCLUSION

The Secretarial Review Decision was based upon the statements of one person – Johnson. Those statements are not contained in credible, unequivocal, contemporaneous documentation of an ongoing investigation related to Costa's clinical judgment or competence. There being no such evidence, the Secretary should have voided, in whole or in part, the allegations in the Correction Report that Costa was under investigation for "recent obstetrical cases" at the time of surrender.

While Johnson may have taken personal offense to Costa's initiation of the recall election of certain board members and Costa's statement in a letter to the editor that a discharged hospital employee was "more valuable than one thousand tinhorn hospital administrators," Costa is entitled to exercise his right to free speech without fear of retaliation in the form of an Adverse Action Report to the Data Bank. Costa's public statements do not constitute a lack of "professionalism." No other evidence of Costa's claimed lack of professionalism was submitted by Johnson. Therefore, the Secretary should have ordered that the Correction Report be voided, in whole or in part, to remove the allegation that Costa's lack of professionalism to nursing and administrative staff was under investigation at the time of surrender.

Costa respectfully moves this court to find and order:

a. That the pleadings and evidence in the administrative record disclose there is no genuine issue as to any material fact and that Costa is entitled to judgment as a matter of law;

b. That the Secretary's refusal to void or correct the Correction Report, in whole or

in part, was unlawful in that said action was arbitrary, capricious, an abuse of discretion, or

otherwise not in accordance with law.

That the predicate conditions for a Data Bank report, as established by § 11133 of c.

the HCQIA were not evidenced in the record by unequivocal, contemporaneous documentation,

and that the Secretary of the United States Department of Health and Human Services erred in

failing to void or correct the Correction Report in whole or in part.

d. That the decision of the Secretary be reversed, and the Correction Report be

voided in whole or in part.

Respectfully submitted,

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Certificate of Service

The undersigned attorney hereby certifies that on April 14, 2006 a true and correct copy of the foregoing Plaintiff's Brief in Support of Motion for Summary Judgment was served upon

defendants' attorney, Paul D. Boeshart, by electronic filing.

BY: / Sally A. Rasmussen

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